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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/974,584	11/19/1997	THOMAS R. CECH	015389-00295	8401

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/12/2003 28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/974,584	CECH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 119-127 is/are pending in the application.

4a) Of the above claim(s) 127 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 119-126 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 11, polynucleotides encoding telomerase reverse transcriptase, corresponding to present claims 119-126, in the response of January 9, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is noted that the claims have been extensively amended and now read generically on polynucleotides encoding a protein having telomerase catalytic activity wherein the polynucleotide is of any origin. It is noted that the previous restriction requirement between particular species of telomerase catalytic protein has NOT been withdrawn. If the claims are amended to recite polynucleotides encoding particular species of the telomerase catalytic protein, the restriction requirement will be reinstated. Claim 127 is withdrawn from consideration as being drawn to a non-elected invention.

2. The Oath/Declaration is not consistent with the information provided in the first line of the specification. The Oath/Declaration indicates that foreign priority is claimed to PCT/US97/17168 and PCT/US97/17885. However, the first line of the specification indicates that the present application is a CIP of each of these PCT applications. The first line of the specification should be amended so that the information set forth therein is consistent with the Oath/Declaration or a new Oath/Declaration should be filed which indicates that the present application is a CIP of PCT/US97/17168 and PCT/US97/17885.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 119-126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

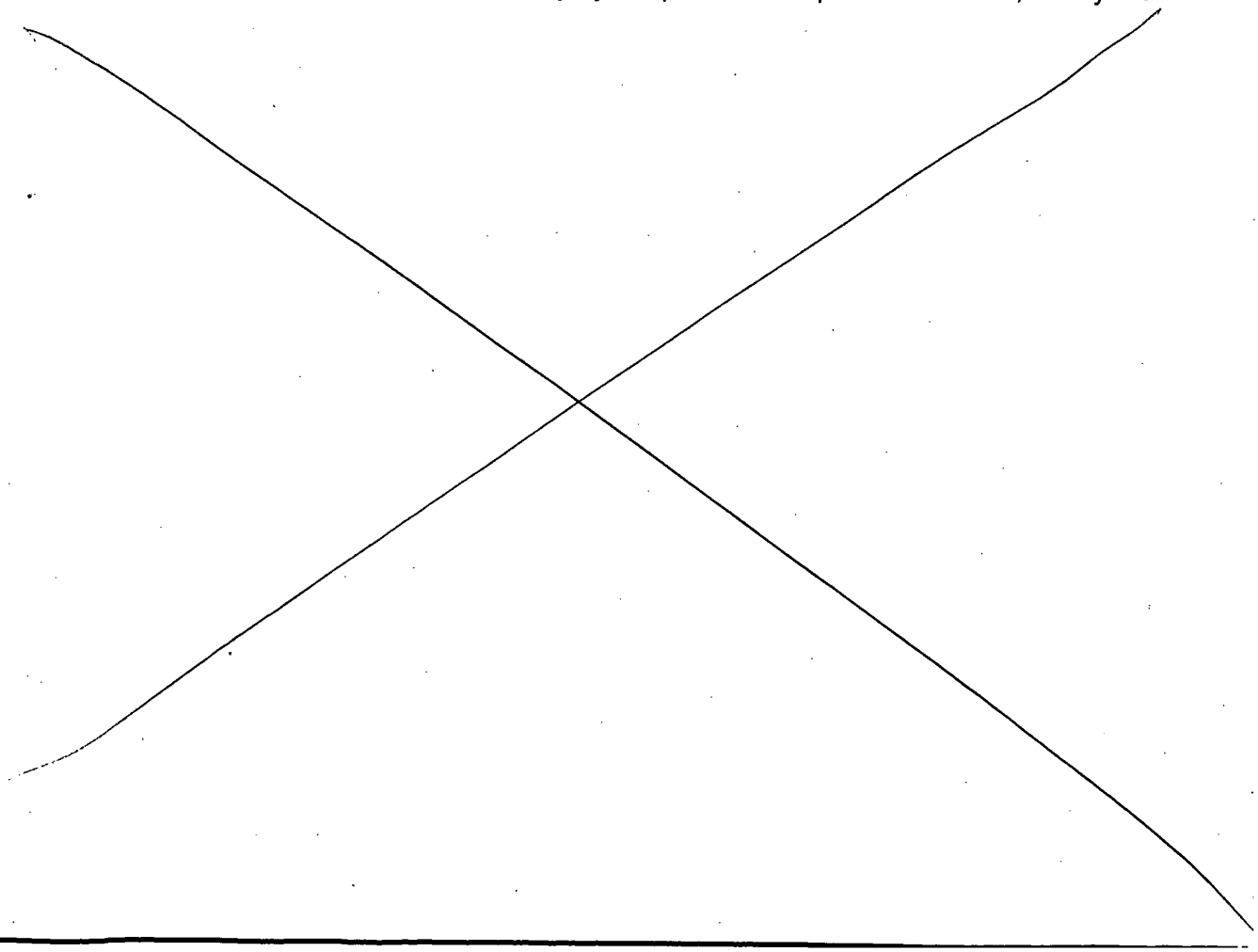
In the instant case, while the specification has defined a limited number of polynucleotides by their structural formula, the specification has not provided an adequate written description of and has not conveyed that at the time of filing applicants were in possession of a representative number of polynucleotides within the broadly claimed genus.

The claims are broadly drawn to polynucleotides encoding a telomerase having telomerase catalytic activity wherein the polypeptide has each of the structures of a) SEQ ID NO: 16 or 17, b) SEQ ID NO: 139, c) SEQ ID NO: 143, d) SEQ ID NO: 144, e) SEQ ID NO: 146, and f) SEQ ID NO: 147. The stated sequences represent conserved motifs shared by telomerase reverse transcriptase (TRT). Each of these sequences include variable amino acid positions which may be any amino acid (X) or may be Leu or Ile (R1), Gln or Arg (R2), Phe or Tyr (R3) or Lys or His (R4), as set forth in claim 119 and in the sequence listing. The amino acids present between these motifs, the exact amino acid sequence of these motifs, the order of the motifs, the length of the amino acid sequence, and the source of the amino acid sequence are not set forth in the claims. The claims include genomic DNA sequences, splice variants, insertion, deletion and substitution variants having an increased or decreased level of telomerase reverse transcriptase activity, and polynucleotides encoding TRTs from any species.

The specification teaches isolated cDNAs encoding telomerase proteins from Euplotes aediculatus, Oxytricha, Saccharomyces cerevisiae, Tetrahymena, Schizosaccharomyces pombe, mouse and human. The specification teaches the genomic DNA encoding E. aediculatus telomerase (SEQ ID NO: 1). The specification

also teaches a single variant of human telomerase wherein the cDNA (SEQ ID NO: 117) encoding this polypeptide has a 182 bp deletion (see, for example, page 38 of the specification).

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, only 7 members of the broadly claimed genus have been defined by their structure. The recitation in the claims of motifs that are present in the encoded TRT does not provide an adequate description of the structure the encoded protein because the claims define broadly conserved sequences but do not define the complete structure of the encoded protein. The function of a protein is governed not only by the presence of particular motifs, but by the



teaches the genomic DNA sequence for one organism, E. aediculatus. However, the claims are inclusive of genomic DNA sequences encoding TRTs from any organism. Accordingly, the specification has not taught the intron, 5' untranslated and 3' untranslated sequences from a representative number of organisms within the broadly claimed genus of a TRT from any organism. Thirdly, the claims include all mutant form of TRTs, such as splice variants, and variants resulting from substitutions, additions or deletions in the amino acid or nucleotide sequence. The variants may have altered telomerase activity, e.g. they may have enhanced or decreased levels of activity. However, the specification teaches only one variant obtained from a human cDNA library, SEQ ID NO: 117 having a 182 bp deletion in its nucleotide sequence. The specification has not taught any non-human TRTs which also include this deletion and has not taught any additional TRT variants or splice variants. With respect to this human protein, the specification (page 38) states that "(a)lthough the hTRT variants lacking the 182 basepair sequence found in the pGRN121 cDNA (SEQ ID NO: 117) are unlikely to encode a fully active telomerase catalytic enzyme, they may play a role in telomerase regulation and/or have partial telomerase activity, such as telomere binding or hTR binding activity." These teachings in the specification make clear the unpredictability in determining the effect of an alteration in the DNA sequence on the functional activity of the encoded protein.

Following, the above analysis, it is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product,

etc.). In the instant case, while the specification and claims define a protein having telomerase reverse transcriptase activity, the specification has not taught the functional activity of any variants. The specification has not sufficiently defined a representative number of splice variants and mutants in terms of additional identifying characteristics. Accordingly, while at the time of filing applicants were in possession of polynucleotides encoding telomerase reverse transcriptase wherein the polynucleotides consist of the sequence of SEQ ID NO: 1 (E. aediculatus p123), SEQ ID NO: 58 (Oxytricha), SEQ ID NO: 66 (S. cerevisiae), SEQ ID NO: 51 or 53 (T. thermophila), SEQ ID NO: 68 (Schizosaccharomyces pombe), SEQ ID NO: 124 (mouse), and SEQ ID NO: 417 (human), the limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of a representative number of polynucleotides within the broadly claimed genus. Therefore, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written

Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

4. Claims 123-126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide basis for the concepts set forth in newly added claims 123-126 of: defining structure c) as limited to SEQ ID NO: 478 (claim 123); defining structure e) as limited to SEQ ID NO: 370 (claim 124); defining structure e) as limited to SEQ ID NO: 479 (claim 125); or for a polynucleotide that encodes a telomerase containing any 10 amino acids of SEQ ID NO: 123 in place of or in addition to the amino acids set forth in claim 119 (claim 126). The specification as originally filed discloses the concept of "isolated naturally occurring and recombinant TRT proteins comprising one or more of the motifs illustrated in Figures 55 and 57." The specification provides an example of the motifs that may be included in said telomerase. However, the specification does not specifically teach that structure c) may be SEQ ID NO: 478, structure e) may be EQ ID NO: 370 and structure f) may be SEQ ID NO: 479. Furthermore, with respect to claim 126, the specification exemplifies a partial cDNA TRT clone encoding a protein having the amino acid sequence of SEQ ID NO: 123. However, the specification does not provide support for the claimed genus of a polynucleotide encoding any TRT comprising any 10 mer amino acid fragment of SEQ ID NO: 123 present in addition to or in place of any one of structures a-f as defined in claim 119.

6. Claims 119-126 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding telomerase reverse transcriptase wherein the polynucleotides comprise SEQ ID NO: 1, 51, 53, 666, 68, 417

or 419, does not reasonably provide enablement for any polynucleotide encoding a protein having telomerase reverse transcriptase activity wherein the polynucleotide comprises the motifs set forth in claim 119. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has not provided sufficient

guidance to enable the skilled artisan to make and use the invention as it is broadly written for the following reasons:

Firstly, it is noted that the claims are drawn broadly to encompass a very large genus of polynucleotides. In particular, the claims are drawn to polynucleotides encoding a telomerase having telomerase catalytic activity wherein the polypeptide has each of the structures of a) SEQ ID NO: 16 or 17, b) SEQ ID NO: 139, c) SEQ ID NO: 143, d) SEQ ID NO: 144, e) SEQ ID NO: 146, and f) SEQ ID NO: 147. The stated sequences represent conserved motifs shared by telomerase reverse transcriptase (TRT). Each of these sequences include variable amino acid positions which may be any amino acid (X) or may be Leu or Ile (R1), Gln or Arg (R2), Phe or Tyr (R3) or Lys or His (R4), as set forth in claim 119 and in the sequence listing. The amino acids present between these motifs, the exact amino acid sequence of these motifs, the order of the motifs, the length of the amino acid sequence, and the source of the amino acid sequence are not set forth in the claims. The claims include genomic DNA sequences, splice variants, insertion, deletion and substitution variants having an increased or decreased level of telomerase reverse transcriptase activity, and polynucleotides encoding TRTs from any species.

The specification teaches a limited number of polynucleotides encoding telomerase reverse transcriptase proteins. Specifically, the specification teaches isolated cDNAs encoding telomerase proteins from Euplotes aediculatus, Oxytricha, Saccharomyces cerevisiae, Tetrahymena, Schizosaccharomyces pombe, mouse and human. The specification also teaches the genomic DNA encoding E. aediculatus

telomerase (SEQ ID NO: 1). Further, the specification also teaches a single variant of human telomerase wherein the cDNA (SEQ ID NO: 117) encoding this polypeptide has a 182 bp deletion (see, for example, page 38 of the specification). The specification provides an alignment of TRT proteins and identifies particular regions within these protein sequences that are conserved amongst TRT proteins. The specification also teaches the general methodology for using known TRT nucleic acids to identify additional TRT nucleic acids.

However, the scope of the claims does not bear a reasonable correlation to the scope of enablement provided by the specification. The teachings in the specification of 7 specific polynucleotides does not enable one of skill in the art to obtain a representative number of polynucleotides within the broadly claimed genus without undue experimentation. The claims are inclusive of polynucleotides which are defined only in terms of the fact that they contain 6 consensus motifs. The claims do not define the overall structure of the protein encoded by the polynucleotide. The claims include splice variant and mutant polynucleotides that contain nucleotide additions, deletions and substitutions. The claims further include variants that have increased or decreased levels or altered telomerase activity as compared to wild-type sequences. However, the specification teaches only one variant human TRT which contains a 182 bp deletion. It is noted that this particular variant appears to be excluded from the claims because the claims require a polynucleotide encoding motif B' (SEQ ID NO: 146) and motif C (SEQ ID NO: 147) and these motifs are not present in the variant having a 182 bp deletion. The specification highlights the unpredictability in determining the effect of nucleotide

alterations on the function of the encoded protein. In particular, the specification at page 38 states that "(a)lthough the hTRT variants lacking the 182 basepair sequence found in the pGRN121 cDNA (SEQ ID NO: 117) are unlikely to encode a fully active telomerase catalytic enzyme, they may play a role in telomerase regulation and/or have partial telomerase activity, such as telomere binding or hTR binding activity." The specification has not identified any particular nucleotides within the TRT gene or cDNA which may be altered without effecting the functional activity of the encoded protein. Furthermore, the specification does not provide sufficient guidance to enable the skilled artisan to determine which alterations in any TRT gene can be made without altering the functional properties of the encoded protein. In view of the breadth of the claims and the unpredictability in the art and lack of specific guidance provided in the specification, undue experimentation would be required to practice the invention as it is broadly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 119-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 119-126 are indefinite over the recitation of "SEQ ID NO: 16 or 17." The recited sequence does not correspond to the specific sequences of SEQ ID NO: 16 and 17. Rather, the version of the sequence containing X_8 corresponds to SEQ ID NO: 16 and the version of the sequence containing X_9 corresponds to SEQ ID NO: 17.

Accordingly, the claim should be amended to recite the sequences containing X_8 and X_9 separately and to clarify that the recombinant polynucleotide encodes a protein which contains either SEQ ID NO: 16 or SEQ ID NO: 17.

Claim 120 is indefinite because it is not clear as to whether the protein includes SEQ ID NO: 116 in addition to the structures a-f or if SEQ ID NO: 116 represents one of the structures of a-f. It is noted that pages 43-44 of the specification describe a TRT which contains either Motif T (which may be defined as SEQ ID NO: 16 or 17) **or** SEQ ID NO: 116.

Claim 121 is indefinite because it is not clear as to whether SEQ ID NO: 477 may be attached at either terminus of SEQ ID NO: 16 or 17 and whether additional amino acids may be inserted between SEQ ID NO: 16/17 and SEQ ID NO: 477.

Claim 122 is indefinite because it is unclear as to the relationship between SEQ ID NO: 473 and structure b). It is unclear as to whether structure b is SEQ ID NO: 473 or if SEQ ID NO: 473 is attached to either terminus of SEQ ID NO: 139 and/or if additional unspecified amino acids may be inserted between SEQ ID NO: 139 and SEQ ID NO: 473. Similarly, claims 123-125 are indefinite because it is not clear as to what is intended to be the relationship between SEQ ID NO: 478 and structure c), SEQ ID NO: 370 and structure e) and SEQ ID NO: 479 and structure f).

Claim 126 is indefinite because it is not clear as to what is intended to be the relationship between SEQ ID NO: 123 and the sequence of the protein set forth in claim 119. SEQ ID NO: 123 is a telomerase protein, which differs from the "wild-type" in that it is encoded by a polynucleotide having a 182 bp deletion. The amino acid sequence of

this protein contains the structures set forth in claim 119. Thereby it is unclear as to whether the polypeptide encoding by the polynucleotide of claim 119 contains at least 10 amino acids of SEQ ID NO: 123 in addition to or in place of any of the structures of the polypeptide set forth in claim 119.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 119-126 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 and 7-10 of U.S. Patent No. 6,261,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '836 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '836. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein

contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '836 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 224 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 224 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '836 are encompassed by the presently claimed polynucleotides encoding any TRT.

9. Claims 119-126 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '809 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '809. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '809 are drawn to polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 1 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 1 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '809 are encompassed by the presently claimed polynucleotides encoding any TRT.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 119-126 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,093,809).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the

University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding Euplotes aediculatus, Schizosaccharomyces, Saccharomyces and human telomerase. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

11. Claims 119-126 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,309,867).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is

no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding Euplotes aediculatus, Schizosaccharomyces, Saccharomyces and human telomerase. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

12. Claim 119 is rejected under 35 U.S.C. 102(a) as being anticipated by Linger et al (Gen Bank Accession No.U95964).

Linger teaches an isolated polynucleotide encoding the p123 telomerase subunit of Euplotes aediculatus. The protein encoded by the polynucleotide of Linger contains the motifs set forth in present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147.

13. Claim 119 is rejected under 35 U.S.C. 102(a) as being anticipated by Lendvay (Genetics (Dec 1996) 144: 1399-1412: cited in the IDS).

Lendvay teaches an isolated polynucleotide EST2 gene encoding the telomerase subunit of Saccharomyces cerevisiae. The protein encoded by the polynucleotide of Linger contains the motifs set forth in present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
August 11, 2003

CARLA J. MYERS
PRIMARY EXAMINER